REMARKS

Responsive to the Office Action dated 05/07/02, applicants have further amended claims 1 and 7. Reconsideration is respectfully requested in view of the amendments and the following remarks.

Claims 1-4 and 7-9 are now pending.

Rejection under 35 U.S.C. 112, second paragraph:

The Examiner rejects claims 1-4 and 7-9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner points out that absence of any delimiter between the method step identifier (e.g., "a" or "b") makes it unclear. In response to this rejection, Applicants have amended the identifier to "a)" as the Examiner suggested.

The Examiner also states that the claimed method steps do not indicate how the comparison to each other group in step h of claim 1 and step e of 7 is interpreted to determine down-regulation of gene expression. In response to this rejection, claim 1 and claim 7 have been further amended to indicate how the down-regulation of gene expression is interpreted. No new matter is added in these amendments to claim 1 and 7. The support can be found at example 1 and 2 in page 15-16 and figure 1-2 of the specification.

Accordingly, applicants respectfully submit that the rejection to claims 1 and 7 under 35 U.S.C. 112, second paragraph, has been overcome and should be withdrawn.

For the same reason, the rejection to claims 2-4, which depend on claim 1, and claims 8-9, which depend on claim 7, should also be withdrawn.

Rejection under 35 U.S.C. 112, first paragraph:

The Examiner rejects claims 1-4, and 7-9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, the Examiner suggests that specific amounts of reagents should be included in the method for producing Product R. To respond this rejection, Applicants have amended claims 1 and 7 as the Examiner suggested. No new matter is added in this amendment. The portions of every reagent in the amended claim 1 and 7 are calculated based on the data in Example 1 at page 9-10, in consideration of the 2.5% variation described in lines 5-6, page 10 of the specification. Any person of ordinary skill in the art would be able to can make any amount of Product R according to the specification.

The Examiner further states that it remains unclear in how the comparison would determine down regulation of gene expression of HIV- coreceptor. As discussed in connection with the rejection under 35 U.S.C. 112, second paragraph, claims 1 and 7 have been amended to specifically recite that a smaller amount of RT-PCR products correlates a lesser of the gene expression. The down regulation of the gene expression of the HIV-coreceptor can be determined according to the amount of RT-PCR products produced from each group of cells treated with different amounts of Product R.

Accordingly, it is respectfully submitted that the rejection to claims 1 and 7 under 35 U.S.C. 112, first paragraph, has been overcome and should be withdrawn.

For the same reason, the rejection to claims 2-4, which depend on claim 1, and claims 8-9, which depend on claim 7, should also be withdrawn.

Allowance of claims 1-4 and 7-9 is respectfully requested.

It is believed that no fees or charges are required at this time in connection with the present application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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AMENDMENTS TO THE CLAIMS SHOWING CHANGES

IN THE CLAIMS:

Please amend claims 1 and 7 as follows:

1. (Four-Times Amended) A method for determining down-regulation of gene expression of a human immunodeficiency virus (HIV) coreceptor, comprising the steps of:

a) culturing cells capable of expressing said human HIV coreceptor;

b) dividing said cultured cells into a plurality of groups;

c) introducing predetermined progressively increasing amounts of Product R at concentrations between 0 to 100%, by volume, to said plurality of groups of said cultured cells, respectively, by electroporation;

d) culturing said plurality of groups of said electroporated cells;

e) preparing a total RNA from each said group of said cultured electroporated cells after step d, respectively;

f) reverse-transcribing the mRNA of said HIV coreceptor from each said total RNA by a reverse transcription-polymerase chain reaction (RT-PCR) to produce an RT-PCR product;

g) measuring the amount of said RT-PCR product produced from each said group of said cells; and

h) comparing each said amount of said RT-PCR product produced from each said group with each other, whereby a lower amount of said RT-PCR product correlates a decrease of said gene expression, wherein Product R is made by a process comprising the steps of:

a) mixing [predetermined amounts] 33.8 to 38.8 parts by weight of casein, 15.3 to 20.3 parts by weigh of beef peptone, 20.3 to 25.3 parts by weight of ribonucleic acid(RNA),

0.9 to 5.9 parts by weight of bovine serum albumin and 0.1 to 5.1 parts by weight of water and 14.6 to 19.6 parts by weight of sodium hydroxide [in a predetermined amount of water];

b') autoclaving the mixture from said step [a] a' until RNA is completely digested;

c') cooling the product from said step b', said cooled product comprising solids;

d') removing said solids from the product from said step c';

e') adding water to the product from said step d'; and

f') adjusting the pH of the product from said step e' to a physiologically acceptable pH range.

7. (Three Times Amended) A method for determining down-regulation of gene expression of a human immunodeficiency virus (HIV) coreceptor, comprising the steps of:

a) dividing cells capable of expressing said human HIV coreceptor into a plurality of groups;

b) introducing predetermined progressively increasing amounts of Product R at concentrations between 0 to 100%, by volume, into said plurality of groups of said cells, respectively, by electroporation;

c) reverse-transcribing the mRNA of said HIV coreceptor of each said groups of said cells by a reverse transcription-polymerase chain reaction (RT-PCR) to produce an RT-PCR product;

d) measuring the amount of said RT-PCR product produced from each said group of said cells; and

e) comparing each said amount of said RT-PCR product produced from each said group with each other, whereby a smaller amount of said RT-PCR product correlates a lesser of said gene expression, wherein Product R is made by a process comprising the steps of:

a') mixing [predetermined amount]33.8 to 38.8 parts by weight of casein, 15.3 to 20.3 parts by weigh of beef peptone, 20.3 to 25.3 parts by weight of ribonucleic acid(RNA), 0.9 to 5.9 parts by weight of bovine serum albumin and 0.1 to 5.1 parts by weight of water and 14.6 to 19.6 parts by weight of sodium hydroxide [in a predetermined amount of water];

b') autoclaving the mixture from said step a' until RNA is completely digested;

c') cooling the product from said step b', said cooled product comprising solids;

d') removing said solids from the product from said step c';

e') adding water to the product from said step d'; and

f') adjusting the pH of the product from said step e' to a physiologically acceptable pH range..